

# Notice of Allowability

Application No.

10/758,217

Examiner

Blessing M. Fubara

Applicant(s)

NOMURA ET AL.

Art Unit

1618

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to communication filed 07/06/05.
2. ☒ The allowed claim(s) is/are 11 and 16-18 (claims are renumbered).
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.


Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date 07/06/05 & 4/24/04
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 09/14/05
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
PO BOX CENTER 1600

Art Unit: 1618

### DETAILED ACTION

Examiner acknowledges receipt request for extension of time, amendment, remarks and IDS, all filed 07/06/05; and supplemental amendment and remarks filed 07/26/05. Claims 11 and 15-20 are pending.

#### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 11, 16-18 and 20, drawn to method of treating infectious disease with penem antibiotic (fuopenem) where the infectious disease is periodontal disease, classified in class 424, subclass 400.
  - II. Claims 15 and 19, drawn to method of treating inflammatory disease with penem antibiotic (fuopenem) where the disease is selected from dermatological, ophthalmological, otolaryngologic, dental/oral and urogenital disease, classified in class 514, subclass 886.

In a telephone interview with applicants' representation on 09/14/05, applicants elected Group I, reserving the right to pursue the non-elected Group in a divisional application.

Applicants' attorney authorized the examiner's amendment on 09/14/05. **The recitation of "periodontal disease" in claim 1 leads to the cancellation of claim 20, which recites "periodontal disease."**

#### EXAMINER'S AMENDMENT

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR

Art Unit: 1618

1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Arthur R. Crawford on 09/14/05.

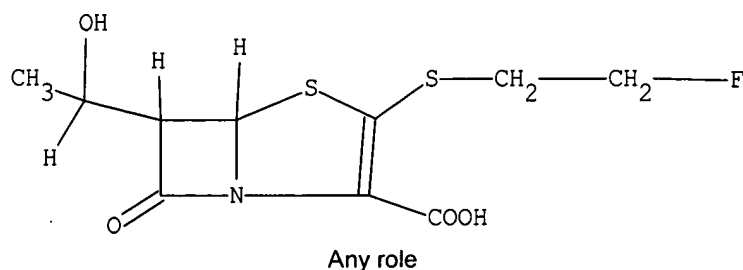
The application has been amended as follows:

In claim 11, after "an" in line 1, delete "infectious disease" and insert ---periodontal disease---

In the claims, cancel claims 15, 19 and 20.

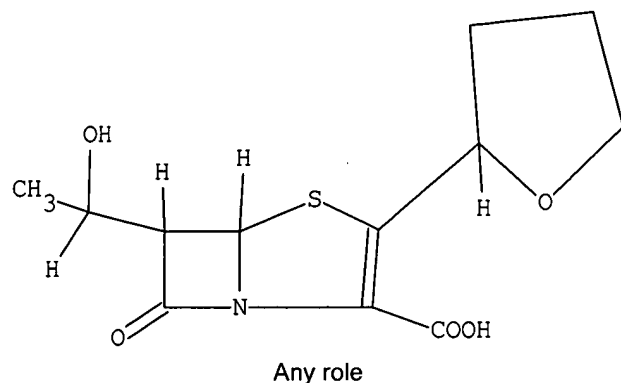
***Allowable Subject Matter***

3. The following is an examiner's statement of reasons for allowance: Girjavallabhan et al. (US 4,411,906) topically treats bacterial infection by administering (5R, 6S, 8R)-6-(1-hydroxyethyl)-2-(fluoroalkylthio)-penem-3-carboxylic acid in an ointment (abstract; column 1, lines 5 and 6; column 2, lines 36-44; column 2, lines 47-68). However, the penem of Girjavallabhan differs from the claimed penem in that the claimed penem is a tetrahydrofuryl while that of Girjavallabhan is fluoroalkylthio as is shown below.



(5R, 6S, 8R)-6-(1-hydroxyethyl)-2-(fluoroalkylthio)-penem-3-carboxylic acid

Art Unit: 1618



(+)-(5R,6S)-6-[(R)-1-hydroxyethyl]-7-oxo-3-[(R)-2-tetrahydrofuryl]-4-thia-1-azabicyclo[3.2.0]hepto-2-ene-2-carboxylic acid.

Shashoua et al. (US 5,795,909) discloses targeting a pharmaceutical agent to a non-central nervous system condition, the pharmaceutical agent is conjugated to cisdocosahexanoic acid (column 4, lines 6-15); faropenem is one of the pharmaceutical agents (column 43, line 48). The mode of administration of the dosage include oral, rectal, sublingual, topical, nasal, transdermal or parenteral routes (column 49, lines 28-31). Shashoua does not disclose the composition in an ointment and does not disclose treating periodontal disease. Therefore, claims 11 and 1-18 are allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

Art Unit: 1618

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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